Remarks

This application has been rejected under 35 U.S.C. §§112 and 102. Claims 39-103 were previously in the application, and the cancellation of those claims obviates the previous rejections. New claims 104-130 have been added by this Amendment, and the previous rejections will be addressed with respect to these new claims.

Claims 39, 55, 70, 81 and 93 were rejected as being vague and indefinite as to the placement of the opaque portion. Without conceding the basis for the rejection, it is noted that those claims have been cancelled and the rejection is thereby obviated. A number of the new claims refer to opaque portions, and each is specific as to the placement of such portions. Claims 108, 114 and 118 indicate that the opaque portions are "generally aligned" with the opposed sides of the capillary channel, and claims 109, 115 and 117 depend directly or indirectly from one of those claims. Claims 110, 116 and 129 indicate that the opaque portions are "aligned" with the sides of the capillary chamber. Claim 122 states that the capillary chamber is bounded on at least three sides by the opaque portions. Claims 127 and 130, and dependent claim 128, define the location of the opaque portions as indicating a portion of the capillary chamber needing to be filled in order to conduct a test. All of these claims therefore sufficiently define the location of the opaque portions – either structurally or functionally – and therefore satisfy §112. Cancelled claims 43, 59, 74, 85 and 97 were rejected under §112 for not being clear as to where the opaque portion extends, but it is submitted that the foregoing comments address this issue with respect to the new claims referring to the locations of opaque portions.

Several claims were rejected as vague and indefinite for failing to indicate what is intended by a color of the opaque portions to contrast with the body fluid. Without conceding

the basis for the rejection, it is noted that those claims have been cancelled and the rejection is thereby obviated. New claims 106, 118 and 122 currently refer to a contrasting color. Claim 106, for example, states that the color "contrasts with the color of the sample as viewed through the viewing material, whereby the user is able to visually locate the sample within the capillary channel by observation through the viewing material." A comparable color contrast is included in claims 118 and 122. This defines the "contrasting" nature of the color, as supported in the specification at Col. 2, lines 5-14: "Preferably, the area of the roof surrounding the window is colored in a way that provides good color contrast between the sample, as observed through the window, and the roof area surrounding the window for ease of identifying sufficient dosing of the strip."

Claims 44, 60, 75, 86 and 98 were rejected for not being clear as to which edge (e.g., right or left) is intended. Without conceding the basis for the rejection, it is noted that those claims have been cancelled and the rejection is thereby obviated. Moreover, it is submitted that none of the new claims 104-130 uses the term "edge" in a manner which is unclear. Claims 104, 107, 112, 113, 119, 126, 127 and 129 refer to the edge which extends about the perimeter of the test strip, i.e., the perimetric edge, as opposed to some type of interior edge. The capillary channel extends to this perimetric edge, i.e., a blood sample can be applied to the test strip along the perimetric edge by contacting the blood with the capillary channel at the sample port.

Prior claims 46, 62 and 87 were rejected for being unclear as to the alignment of the opaque portions. Without conceding the basis for the rejection, it is noted that those claims have been cancelled and the rejection is thereby obviated. New claims 108, 110, 114, 116, 118 and 129 refer to the alignment of the opaque portions, and they are clear as to the nature

of the alignment. In particular, the alignment of the opaque portions is with respect to the sides of the capillary channel.

As will be appreciated from the disclosure, the present invention provides a test strip in which the user is able to visualize the filling of the capillary channel in a way that makes it apparent whether the test strip has been sufficiently filled as to be able to produce an accurate test. As discussed more fully hereafter, the test strip therefore includes a viewing area which corresponds with at least the area of the capillary channel – up to the area of the test reagent and electrodes – to allow the user to see that the blood sample has sufficiently filled the test area. This would be in contrast, for example, with a test strip in which the entire upper layer is transparent and the user is not able to differentiate between the area of the test strip that needs to be filled with blood versus other areas of the test strip which do not need to be filled.

Finally, claims 48, 68 and 99 were rejected under §112 for failing to clearly indicate the relationship between the opaque and visualization portions. Without conceding the basis for the rejection, it is noted that those claims have been cancelled and the rejection is thereby obviated. The new claims 104-130 include opaque portions which define a fill area, as well as variously worded means or structures for viewing the fill area. The relationship is clear from the disclosure and from the claims. As indicated in the prior paragraph, the opaque portions are provided such that the user's view of the interior of the test strip allows the viewer to see an area which is to be filled for the test strip to work properly. The opaque portions are therefore at least generally aligned with the sides of the capillary channel, although it is not required for this purpose that the opaque portions be precisely aligned with the capillary channel. In certain claims, the location of the opaque portions is more

specifically indicated to be in alignment with the sides of the capillary channel, as opposed to being in general alignment.

The cancelled claims were also previously rejected under §102 on the basis of several cited patent references. The cancellation of those claims has obviated these rejections. New claims have been submitted in an effort to further focus the examination of this application. Applicant submits that the basic limitations of the new claims were contained in the cancelled claims, and the new claims are being submitted in an effort to clarify the present invention. Applicant will therefore comment on the cited patents in respect to new claims 104-130.

As a preliminary comment, applicant notes that all of the devices described in the cited patent references are distinguishable from the present invention in the respect that they fail to disclose or suggest a capillary-fill, electrochemical test strip in which the movement of a blood sample to the electrodes and test reagent can be visualized to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area, such that the test results can be accurate. Electrochemical test strips are unique as compared to test strips involving color change, fluorescence or other reaction indicators involving direct viewing of the test site. Those test strips naturally have an area for visualizing the test area because the results are detected in that manner. Such test devices will therefore provide some amount of visibility to the test area. But the cited art has not taught or suggested a configuration in which the area viewable by the user for a capillary-fill device distinguishes the area of the capillary up to the test area to be filled in order to sufficiently dose the electrodes and reagent of an electrochemical test strip, as opposed to other areas not needing to be filled.

The Poto patent (5,728,352) has been cited against the previous claims, but Poto is clearly distinguished from the present invention. Poto is typical of the "top dosing" prior art test strips in which the blood sample is applied directly to the planar surface of the test area. There is no capillary filling of the test strip, and therefore there is no need (or opportunity) to view the filling of the test strip to ensure that a sufficient amount of blood has reached the test area. The present invention specifically addresses capillary fill electrochemical test strips, where problems of inadequate dosing of blood can lead to erroneous results because there is insufficient blood covering the reagent and the working/counter electrodes. Applicant submits that the present invention is thereby distinguished from, and patentable over, the Poto reference, and more importantly that new claims 104-130 patentably define over the Poto patent.

Specifically, Poto was cited as teaching a test strip including a "test spot area (20)" and a "reading aperture (46)". The test spot area was read as corresponding to the "application port", as that term was used in the prior claims. However, the present claims make it clear that the invention involves a test strip in which there is a capillary channel which extends to a perimetric edge of the test strip, and that the sample application port opens along that perimetric edge. The "test spot area (20)" in the Poto patent is an interior surface area upon which the blood is directly deposited. It does not extend to the perimetric edge as claims 104-130 require. The "reading aperture (46)" of the Poto patent does not correspond to a visualizing means or structure as recited in claims 104-130, as it is an aperture in the meter, and not in the test strip. (See column 5, line 41, stating "a test reading aperture 46, FIG. 6, in the instrument.") More importantly, there is no disclosure in Poto that teaches or

suggests a solid, transparent or translucent material overlying a capillary channel which enables the user to view the blood as it fills the channel.

Douglas (5,843,691) has been cited as showing a multilayer colorimetric reagent test strip teaching opaque and transparent regions (as well as a vent). Douglas moves the blood sample by a "metering means" which distributes the sample along the strip to a series of test areas. However, the Douglas device is readily distinguished from the present invention. In Douglas, the test strip includes several discrete test sites, each of which is intended to be contacted by the blood sample. The difference in the sites is that successive ones include increasing amounts of an inhibitor to the color change reaction. Therefore, "a correspondingly increasing analyte concentration must be contained in a sample if it is to effect a color change" at subsequent test sites. See column 3, lines 24-35. Thus, Douglas does not provide a means for visualizing the filling of a test strip, since it would be unclear whether the blood sample reached a particular test cite, or if the blood sample simply did not have enough analyte as to cause a color reaction at that test cite. Therefore, a user of the Douglas device would not know if a test site did not show a color reaction because of the lack of analyte in the blood, or the lack of blood at the test site – and this could lead to an erroneous test reading.

Douglas also fails to include a visualization material that extends from adjacent the sample application port to the test area. Douglas instead includes spaced apart holes 38, and it is not possible to view any progress of the blood between the test areas. The Douglas patent is therefore further distinguished to the extent that the present claims require that the view of the capillary channel extends from at least adjacent the sample application port to the test area.

Further, Douglas does not include a solid, transparent or translucent material overlying a capillary channel, but rather simply includes a series of holes 38 which align with the "bibulous areas" to make any color change visible. See column 12, lines 57-65. In contrast, the present invention provides such a solid viewing material which has the advantage of providing both a cover over the capillary channel and an area to view the filling of the capillary channel.

The patent to Columbus (4,323,536) has been cited as teaching a capillary device including an opaque layer 56. However, Columbus does not teach or suggest the present invention in several respects. The Columbus device does not include a sample application port along the perimetric edge, but rather doses blood to the device through an interior aperture 46. The filling of the capillary channels in Columbus is not viewable in the manner of the present invention. While the support member 12 in Columbus is preferably transparent, there is no indication that some portion of the device is provided that is opaque in the area surrounding the capillary channel(s). Thus, the device suffers from the problem, mentioned earlier, that a user looking at the support member 12 would not know which parts of the device should be filling with blood and which parts need not. Moreover, the layer 56 has been cited as being opaque, but this layer does not surround the fill channel. Instead, it is actually located on top of the reagent layer 54 – and therefore could not permit visualization of the test area which it is on top of.

Terry (5,229,299) has been cited as teaching a test device comprising a reagent paper sandwiched between two sheets of transparent or translucent plastic, in which the paper may be opaque. The Terry device is readily distinguished from the present invention. Terry suffers the same disadvantage as other prior art devices, including the Columbus patent.

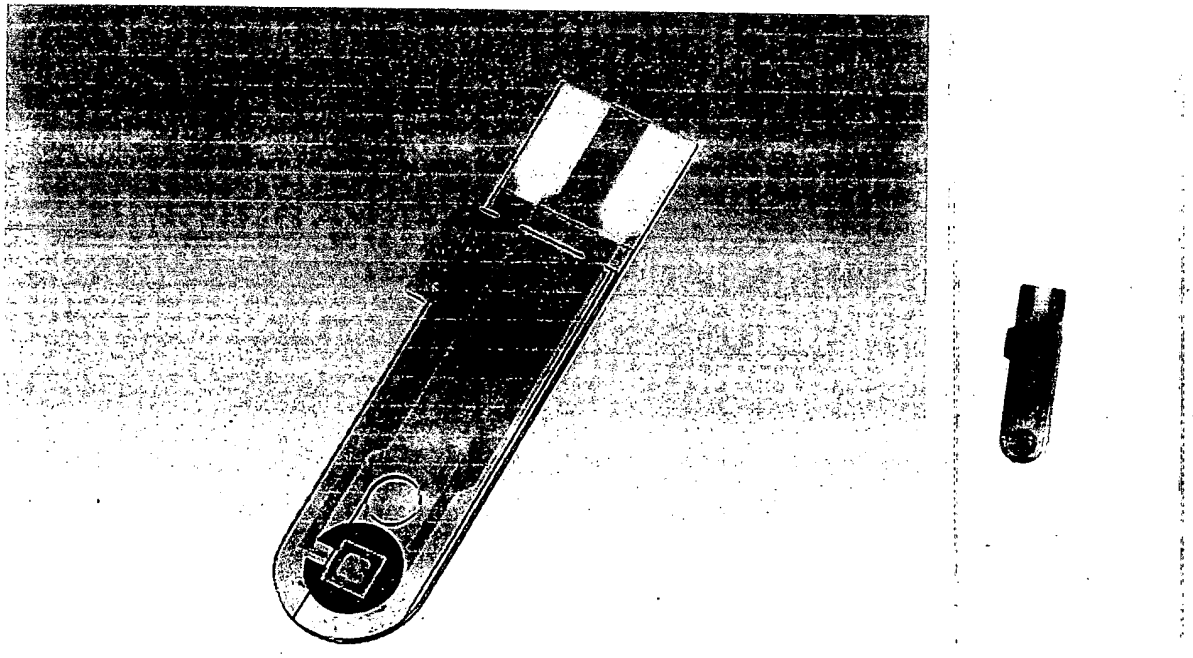
While Terry discloses transparent or translucent outer sheets of plastic, there are no opaque portions indicating to the user which interior parts of the device comprise a capillary channel to be filled. Instead, the entire outer surfaces are transparent or translucent. The cited opacity is not in an area surrounding a capillary channel, but rather is the reagent paper which fills the capillary channel. In addition to the physical differences between Terry and the inventions set forth in new claims 104-130, Terry fails to achieve a function of the claimed invention – that an electrochemical test strip can be visually monitored to ensure that a sufficient amount of blood reaches the electrodes and the test reagent.

The cited Churchouse patent (5,310,525) similarly fails to describe or teach a test device in which a test liquid can be viewed as it fills a capillary channel. Churchouse discloses a test device in which a detecting layer and a spreading layer are sandwiched between two sheets, at least one of which can be transparent. However, there is again no indication or suggestion that the device is configured with opaque portions to enable the user to distinguish the filling of a capillary channel in a test strip. While Churchouse teaches that one of the outer sheets may be opaque, it only speaks in terms of the entire sheet being opaque, meaning that the capillary filling would not be viewable at all from that side. In addition to these distinctions, Churchouse tracks with other prior art in that it fails to allow the user to know if there is limited analyte being detected, or if the device is simply not filling properly or sufficiently.

The Cox patent (5,366,902) was cited as teaching a device including a capillary bore leading to a reagent pad, with some portions of the device being transparent or translucent, and other portions being opaque. However, the transparent/translucent and opaque portions are not provided in the manner of the present invention. The Cox device has a capillary

channel 3 which leads from a "cup" 2 to a reagent pad 9. This capillary channel is formed in a body member which may be metal, glass or plastic (column 2, lines 12-16). There is no indication or suggestion that any portion of this body member should be made opaque in order to allow a user to distinguish when a liquid sample is properly filling through the capillary chamber to the test site. This device suffers from the same problem as other prior art devices previously discussed.

In addition to the cited art, applicant has determined that a prior art device marketed by Bayer Corporation under the trademark GLUCOMETER ELITE® was being sold more than a year before the earliest priority date for this application, and therefore constitutes prior art under §102(b). Below is a picture of the Glucometer Elite product, and an actual sample of the device is attached hereto on the right side of the below picture. Also presented on the

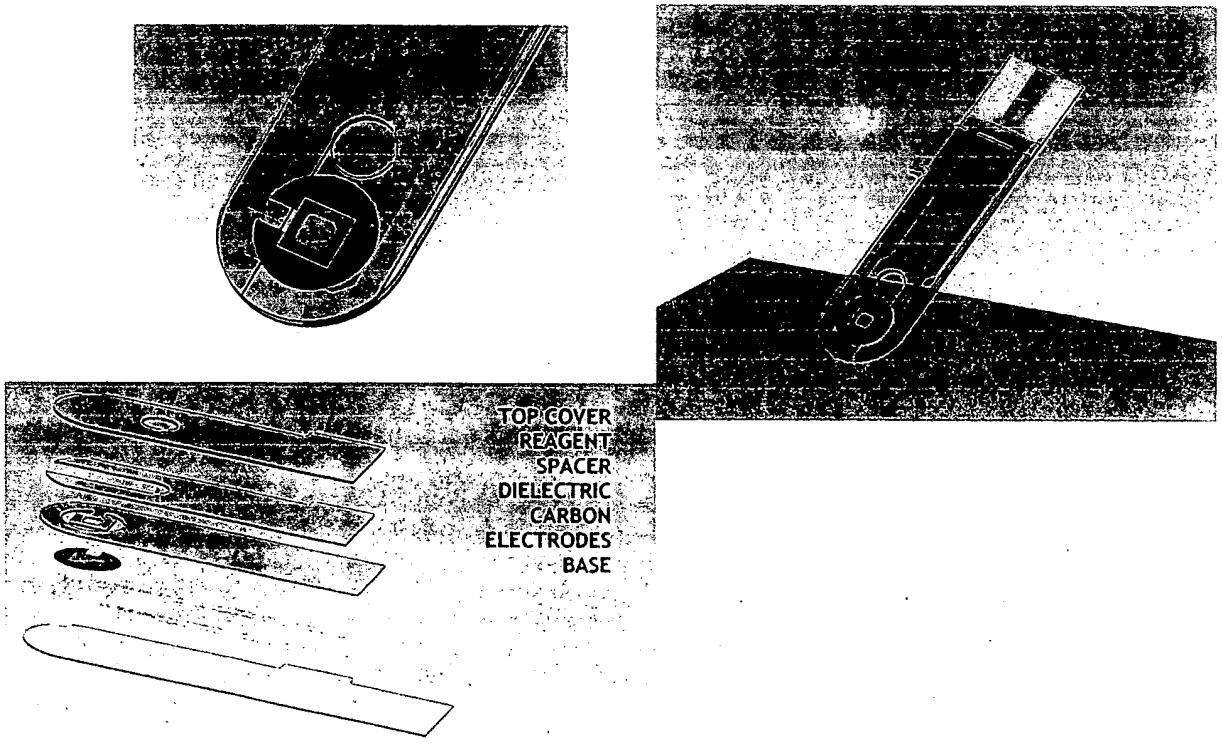


following page are additional views of the Elite product, including an exploded view showing what are believed to be 7 distinct components of the strip.

Applicant submits these materials in a good faith effort to enable the patent examiner to understand the construction of the Glucometer Elite product, and applicant believes the depictions to be accurate. If there are differences between these depictions and the actual Glucometer Elite device, it is believed that they would not exist as to issues relating to consideration of the Elite device as prior art to the present invention, as further explained below.

The Glucomete Elite product is an electrochemical test strip including a pair of electrodes received at the end of a capillary channel which extends to a sample application port at the perimetric edge of the test strip. The Elite device includes several layers, including a spacer and a top cover. It appears clear that the spacer and top cover are both transparent

GLUCOMETER ELITE



materials, as the components underneath these layers are visible. For example, the electrodes, the carbon layer, and the dielectric (which shields portions of the electrodes from the capillary channel) are all located below the spacer, and yet all are visible in the assembled test strip.

To the extent that the Glucometer Elite product includes opacity, it is in components that lay below the spacer which defines the capillary channel. More importantly, there is nothing in the Glucometer Elite test strip which comprises opaque portions or colored portions which distinguish the capillary fill channel from other parts of the test strip. Thus, when blood is dosed to the Glucometer Elite strip, the user would be able to see blood moving into the strip, but would not be able to tell if it was filling the capillary channel or some lesser portion of the interior of the strip.

In contrast, the present invention is directed to a test strip which includes opaque portions specifically located to enable the user to monitor whether sufficient dosing of the test area of the strip has been accomplished. This function is stated at various locations in the disclosure, including the following:

> "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip." Column 8, line 61 to column 9, line 9.

This feature is contained in all of the pending claims of this application. For example, claim 104 identifies "visualization means associated with the capillary channel for enabling a

user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test". Various claims specify aspects of opaque and/or colored portions which delimit the viewing area such that confirmation of sufficient fill is readily achieved. Claims 110 and 116, for example, define a test strip which includes opaque portions that are aligned with the opposed sides of the capillary channel. As a further example, claim 127 requires the following:

> said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;
>
> said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test;
>
> wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.

These claim limitations distinguish the present invention from the Glucometer Elite test strip, which includes a spacer and a top cover which are both transparent. The Glucometer Elite test strip fails to provide opaque and/or colored portions which define a viewing area that confirms sufficient filling of the test strip when that viewing area has been filled with the blood sample. The opaque portions of the Glucometer Elite strip are not aligned with the sides of the capillary channel, and are not otherwise configured to provide the features set forth in claims 104-130.

The present invention is therefore seen to be uniquely distinguished from the above-described prior art. Reconsideration of the application and allowance of new claims 104-130 is therefore respectfully requested.

Respectfully submitted,

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